



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of inventor Peart et al.

Serial No. 10/759,280

Group Art Unit: unassigned

Filed: 01/20/2004

Examiner: unassigned

For: " **Δ^9 TETRAHYDROCANNABINOL (Δ^9 THC) SOLUTION METERED DOSE
INHALERS AND METHODS OF USE**"

Mail Stop Petitions
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**PETITION UNDER 37 C.F.R. § 1.181-1.183 IN RESPONSE TO NOTICE OF
INCOMPLETE APPLICATION**

Dear Sir:

This petition is in response to a Notice of Incomplete Application mailed April 22, 2004. It is respectfully requested that the application be accorded a filing date of January 20, 2004 and benefit of priority of U.S. patent 6,713,048. It is also respectfully requested that the formal drawings submitted concurrently be accepted together with accordance of the January 20, 2004 filing date without submission of a newly executed oath or declaration.

Applicant notes that the Notice of Incomplete Application asserts that drawings were not included with the application and original declaration submitted with the application as filed on January 20, 2004, and requests filing of a newly executed oath or declaration. However, Applicant further notes that the original oath covers the incorporation by reference of the parent application, which, in turn, covers the drawings of the original application. Therefore, since the originally filed declaration covers the drawings, Applicant respectfully submits that there is no need for a newly executed oath or declaration.

06/24/2004 AAD0F01 00000044 10759280

01 FC:1460

130.00 OP

-1-

**TRANSMITTAL LETTER
(General - Patent Pending)**

Docket No
02940086CA

In Re Application Of: **J. Peart, et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/759,280	January 20, 2004	Unassigned	30743	Unassigned	6861

Title: **DELTA9 TETRAHYDROCANNABINOL (DELTA9 THC) SOLUTION METERED DOSE INHALERS
AND METHODS OF USE**



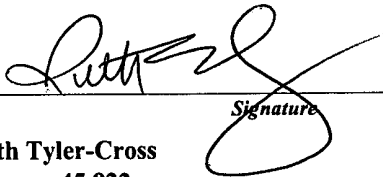
COMMISSIONER FOR PATENTS:

Transmitted herewith is:

**PETITION IN RESPONSE TO NOTICE OF INCOMPLETE APPLICATION; PETITION FEE \$130.00;
EXHIBITS A-C**

in the above identified application.

- ☐ No additional fee is required.
- ☒ A check in the amount of **\$130.00** is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. **50-2041**
as described below.
- ☐ Charge the amount of
- ☒ Credit any overpayment.
- ☒ Charge any additional fee required.


Signature

**Ruth Tyler-Cross
Reg no. 45,922
Whitham, Curtis & Christofferson, P.C.
11491 Sunset Hills Road, Suite 340
Reston, Virginia 20190
703-787-9400**

Dated: **June 22, 2004**

I certify that this document and fee is being deposited
on with the U.S. Postal Service as
first class mail under 37 C.F.R. 1.8 and is addressed to the
Commissioner for Patents, P.O. Box 1450, Alexandria, VA
22313-1450.

Signature of Person Mailing Correspondence

HAND DELIVERED

Typed or Printed Name of Person Mailing Correspondence

CC:

10/759,280

The facts of the case are as follows:

1. On January 20, 2004, Applicant filed the above-referenced patent application in the USPTO. The application, U.S. 10/759,280, is a continuation of US patent application 09/944,221 which matured into U.S. patent 6,713,048 on March 30, 2004. U.S. patent 6,713,048 and application 09/944,221 as originally filed included 8 sheets of drawings containing Figures 1-2, 3A-D, 4A-D, 5, 6A-6B, and 7A-N. Copies of the drawings from U.S. patent 6,713,048 are herewith attached as Exhibit A.
2. On April 22, 2004, subsequent to issuance of the parent application, a Notice of Incomplete Non-provisional application was mailed indicating that the filing date of January 20, 2004, was not accorded to U.S. 10/759,280 due to the absence of drawings.
3. The complete contents of the parent application were incorporated by reference in the present application (10/759,280) at the time of filing. This is evidenced by:
 - a) the checking of Boxes numbered 4b and 5 of the Transmittal Letter that accompanied the application (copy enclosed as Exhibit B). Box 5 reads as follows:

“Incorporation By Reference (usable if Box 4b is checked)

The entire disclosure of the prior application, from this a copy of the oath of declaration is supplied under box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.”

AND

- b) the amendment to the specification that was included in the Preliminary amendment that was filed concurrently with the application (copy enclosed as Exhibit C). The amendment to the specification reads as follows:

“Amendments to the Specification:

Please delete the paragraph entitled “Cross Reference to Related Applications” on page 1, at lines

10/759,280

7-9, and replace the deleted paragraph with the following replacement paragraph:

This application is a continuation of pending U.S. serial No. 09/944,221, which is a continuation-in-part of pending U.S. serial number 09/273,766, now issued U.S. patent 6,509,005, which claims priority of U.S. provisional application serial No. 60/105,850 filed October 27, 1998, and the complete content of those applications are incorporated herein by reference.”

4. The undersigned declares that all statements made herein of their own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent resulting therefrom.

REMARKS

It is respectfully submitted that Applicant is entitled to a filing date of January 20, 2004 since drawings are not necessary to an understanding of the subject matter sought to be patented and, in any case, drawings were, in fact, constructively provided by virtue of the incorporation by reference in the application papers filed on January 20, 2004. It is also respectfully submitted that accordance of a filing date of January 20, 2004 is well-justified under 37 C.F.R. 1.183 to prevent manifest prejudice to Applicant in loss of copendency with the parent application.

Given the above facts, Applicant submits that at the time of filing, the complete contents of the parent application were incorporated by reference into the present application. Applicant therefore respectfully requests that the present application be amended to include the drawings of the parent application 09/944,221 and that the application be accorded a filing date of January 20, 2004.

Applicant also respectfully submits that the drawings of the application are not necessary for understanding of the subject matter sought to be patented. The subject matter of the claims is directed to methods of administering pharmaceutically effective doses of aerosolized

tetrahydrocannabinol using a novel formulation (including up to 15% by weight of a solvent). As can be readily appreciated from the Brief Description of the Drawings, the respective figures are largely indicative of the efficacy of the invention from test data, and are thus largely redundant over data presented in the tables and in the specification.

For example, the results presented graphically in **Figure 1** of the drawings are also presented numerically in Tables 4A and 4B in the specification (pages 16-17). Line 16 of page 15 of the application states: "The results are given in Figure 1 and Tables 4A and 4B". Lines 8-9 of page 16 of the application state "However, the data presented in Figure 1 and Table 4 show that"

Figure 2 of the drawings is a generic depiction of a device for use in carrying out the methods of the invention. Lines 21-22 of page 19 of the application states the "Figure 2 provides a generalized drawing of an MDI containing the composition of this invention ...". Further, lines 14-16 of page 19 state that: "The containers for the formulations of the instant invention may be any that are suitable for the efficacious delivery of aerosol inhalants. Several containers and their method of usage are known to those of skill in the art."

The experimental results presented in **Figures 3A-D**, **Figures 4A-D**, and **Figure 5** of the drawings are discussed in the specification on page 25 at lines 6-12, lines 13-18, and lines 19-21, respectively. The results are readily understandable from the discussion alone without reference to the drawings, and are also presented in part in Tables 6 and 7 of the application (pages 25-27).

Figures 6A-B and depict the chemical formulas of the propellants HFA 134a and HFA 227, both of which are known in the art. **Figures 7A-N** depict derivatives and substitutes of Δ^9 THC which may be used in the practice of the present invention. All the chemical structures which are depicted are known in the art.

In summary, the drawings are principally relevant to an understanding of the efficacy of the invention but are not necessary for understanding the invention itself as claimed. They are largely graphic depictions of data otherwise provided in the papers filed on January 1, 2004.

Applicant submits that an understanding of the novel methods of the invention can be attained from the support in the specification of the application, even in the absence of the

10/759,280

drawings. In this regard, where the subject matter admits of illustration but is not necessary to an understanding of the invention, 35 USC 113 supports the submission of drawings within a period of not less than two months from the date of a requirement for illustration. Accordingly, formal drawings exactly corresponding to the drawings in U.S. 6,713,048 are being concurrently filed. It is respectfully submitted that such a submission is not inconsistent with this petition and the accordance of a filing date of January 20, 2004, to this application (notwithstanding the assertion in the Notice that the filing date accorded would be the date of the submission), particularly in view of the incorporation by reference discussed above. On the contrary, the presence of the drawings in the incorporated U. S. Patent clearly establishes that later submission cannot be relevant to overcoming any insufficiency of disclosure or supplementing the original disclosure for the purpose of interpreting any claim.

Finally, since the drawings were constructively included in the original application papers and later submission is expressly permitted under 35 USC 113, accordance of a filing date of January 20, 2004, in response to this petition and acceptance of a concurrent submission of drawings is clearly warranted to prevent prejudice to Applicant in view of the mailing date of the Notice of Incomplete Application.

A check for \$130.00 is attached hereto to pay the petition fee. If any additional fees are due for granting the petition, granting the filing date, or entering page 17, the Commissioner is authorized to charge attorney's deposit account #50-2041.

Respectfully submitted,



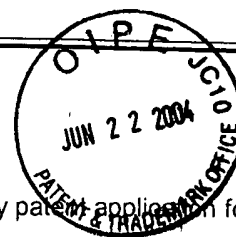
Ruth E. Tyler-Cross

Reg. No. 45,922

Exhibit B (two pages)

UTILITY PATENT APPLICATION TRANSMITTAL
(Large Entity)*(Only for new nonprovisional applications under 37 CFR 1.53(b))*Docket No.
02940086CA

Total Pages in this Submission

TO THE COMMISSIONER FOR PATENTSMail Stop Patent Application
P.O. Box 1450
Alexandria, VA 22313-1450

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled:

DELTA9 TETRAHYDROCANNABINOL (DELTA9 THC) SOLUTION METERED DOSE INHALERS AND METHODS OF USE

and invented by:

Joanne Peart, Peter R. Byron, Aron H. Lichtman, Billy R. Martin

If a **CONTINUATION APPLICATION**, check appropriate box and supply the requisite information:☒ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: 09/944,221

Which is a:

☐ Continuation ☐ Divisional ☒ Continuation-in-part (CIP) of prior application No.: 09/273,766

Which is a:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: _____

Enclosed are:

Application Elements

1. ☒ Filing fee as calculated and transmitted as described below
2. ☒ Specification having 35 pages and including the following:
 - a. ☒ Descriptive Title of the Invention
 - b. ☒ Cross References to Related Applications (if applicable)
 - c. ☐ Statement Regarding Federally-sponsored Research/Development (if applicable)
 - d. ☐ Reference to Sequence Listing, a Table, or a Computer Program Listing Appendix
 - e. ☒ Background of the Invention
 - f. ☒ Brief Summary of the Invention
 - g. ☒ Brief Description of the Drawings (if filed)
 - h. ☒ Detailed Description
 - i. ☒ Claim(s) as Classified Below
 - j. ☒ Abstract of the Disclosure

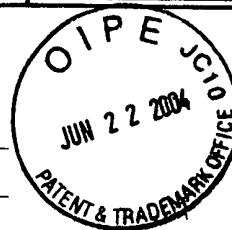
UTILITY PATENT APPLICATION TRANSMITTAL (Large Entity)

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Docket No.
02940086CA

Total Pages in this Submission

Application Elements (Continued)



3. ☐ Drawing(s) (when necessary as prescribed by 35 USC 113)
- a. ☐ Formal Number of Sheets _____
- b. ☐ Informal Number of Sheets _____
4. ☒ Oath or Declaration
- a. ☐ Newly executed (original or copy) ☐ Unexecuted
- b. ☒ Copy from a prior application (37 CFR 1.63(d)) (for continuation/divisional application only)
- c. ☐ With Power of Attorney ☐ Without Power of Attorney
- d. ☐ DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) named in the prior application,
see 37 C.F.R. 1.63(d)(2) and 1.33(b).
5. ☒ Incorporation By Reference (usable if Box 4b is checked)
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.
6. ☐ CD ROM or CD-R in duplicate, large table or Computer Program (Appendix)
7. ☐ Application Data Sheet (See 37 CFR 1.76)
8. ☐ Nucleotide and/or Amino Acid Sequence Submission (if applicable, all must be included)
- a. ☐ Computer Readable Form (CRF)
- b. ☐ Specification Sequence Listing on:
- i. ☐ CD-ROM or CD-R (2 copies); or
- ii. ☐ Paper
- c. ☐ Statement(s) Verifying Identical Paper and Computer Readable Copy

Accompanying Application Parts

9. ☒ Assignment Papers (cover sheet & document(s))
10. ☐ 37 CFR 3.73(B) Statement (when there is an assignee)
11. ☐ English Translation Document (if applicable)
12. ☒ Information Disclosure Statement/PTO-1449 ☐ Copies of IDS Citations
13. ☒ Preliminary Amendment
14. ☒ Return Receipt Postcard (MPEP 503) (Should be specifically itemized)
15. ☐ Certified Copy of Priority Document(s) (if foreign priority is claimed)
16. ☐ Certificate of Mailing
- ☐ First Class ☐ Express Mail (Specify Label No.): HAND DELIVERED

Amendments to the Specification:

Please delete the paragraph entitled "Cross Reference to Related Applications" on page 1, at lines 7-9, and replace the deleted paragraph with the following replacement paragraph:

This application is a continuation of pending U.S. serial No. 09/944,221, which is a continuation-in-part of pending U.S. serial number 09/273,766, now issued U.S. patent 6,509,005, which claims priority of U.S. provisional application serial No. 60/105,850 filed October 27, 1998, and the complete content of those applications are incorporated herein by reference.